UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/938,677	08/24/2001	Robert H. Harris	13095	2566

7590 09/17/2003

Scully, Scott, Murphy & Presser
400 Garden City Plaza
Garden City, NY 11530

EXAMINER
LUKTON, DAVID

ART UNIT	PAPER NUMBER
1653	

DATE MAILED: 09/17/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/938,677	HARRIS, ROBERT H.	
	Examiner	Art Unit	
	David Lukton	1653	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *22 January 2002* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-72* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-72* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

A restriction is imposed, as set forth below. First, however, the following subgenera are defined:

G1: R is hydrogen or lower alkyl, and R is substituted;

G2: R is hydrogen or lower alkyl, and R is unsubstituted;

G3: R1 is hydrogen or lower alkyl, and R1 is substituted;

G4: R1 is hydrogen or lower alkyl, and R1 is unsubstituted;

G5: the substituents can vary as the claims permit, provided that G1 - G4 are excluded;

G6: The disorder is pain, a headache, or bipolar disease;

G7: The disorder can be whatever is permitted by claim 50, provided that G6 is excluded

*

Restriction to one of the following inventions is required under 35 U.S.C. §121:

1. Claims 1-4, 6-8, 11-13, 15-19, 51, 55, 58, drawn to a method, limited to compounds in which R is limited to G1.

2. Claims 1-4, 6-8, 11-13, 15-19, 51, 55, 58, drawn to a method, limited to compounds in which R is limited to G2.

3. Claims 1-4, 6-8, 11-13, 15-19, 51, 55, 58 drawn to a method, limited to compounds in which R1 is limited to G3.

4. Claims 1-19, 51, 55, 58, drawn to a method, limited to compounds in which R1 is limited to G4.

5. Claims 1-4, 6-8, 11-13, 15-19, 51, 55, 58, drawn to a method, limited to G5.

6. Claims 20-23, 25-27, 29-31, 34, 52, 56, 59-67, drawn to a method, limited to compounds in which R is limited to G1.

7. Claims 20-23, 25-27, 29-31, 34, 52, 56, 59-67, drawn to a method, limited to compounds in which R is limited to G2.

8. Claims 20-23, 25-27, 29-31, 34, 52, 56, 59-67, drawn to a method, limited to compounds in which R1 is limited to G3.

9. Claims 20-34, 52, 56, 59-67, drawn to a method, limited to compounds in which R1 is limited to G4.

10. Claims 20-23, 25-27, 29-31, 34, 52, 56, 59-67, drawn to a method, limited to G5.

11. Claims 35-38, 40-42, 44-46, 49, 53, 57, 68-72, drawn to a method, limited to compounds in which R is limited to G1.

12. Claims 35-38, 40-42, 44-46, 49, 53, 57, 68-72, drawn to a method, limited to compounds in which R is limited to G2.

13. Claims 35-38, 40-42, 44-46, 49, 53, 57, 68-72, drawn to a method, limited to compounds in which R1 is limited to G3.

14. Claims 35-49, 53, 57, 68-72, drawn to a method, limited to compounds in which R1 is limited to G4.

15. Claims 35-38, 40-42, 44-46, 49, 53, 57, 68-72, drawn to a method, limited to G5.

16. Claims 50 and 54, drawn to the method of G6, wherein the method of G6 is limited to

compounds in which R is limited to G1.

17. Claims 50 and 54, drawn to the method of G6, wherein the method of G6 is limited to compounds in which R is limited to G2.

18. Claims 50 and 54, drawn to the method of G6, wherein the method of G6 is limited to compounds in which R1 is limited to G3.

19. Claims 50 and 54, drawn to the method of G6, wherein the method of G6 is limited to compounds in which R1 is limited to G4.

20. Claims 50 and 54, drawn to the method of G6, wherein the method of G6 is limited to compound that are limited to G5.

21. Claims 50 and 54, drawn to the method of G7, wherein the method of G7 is limited to compounds in which R is limited to G1.

22. Claims 50 and 54, drawn to the method of G7, wherein the method of G7 is limited to compounds in which R is limited to G2.

23. Claims 50 and 54, drawn to the method of G7, wherein the method of G7 is limited to compounds in which R1 is limited to G3.

24. Claims 50 and 54, drawn to the method of G7, wherein the method of G7 is limited to compounds in which R1 is limited to G4.

25. Claims 50 and 54, drawn to the method of G7, wherein the method of G7 is limited to compound that are limited to G5.

The claimed inventions are distinct. First, a substantial portion of the compounds to which the method claims are drawn are known in the prior art. Second, each of claims 1, 20, 35, and 50 is drawn to a method for treating a different disorder. Third, many of the compounds (to which the claims are drawn) are known for the purposes recited in the claims. One of the principle reasons for lack of novelty is the recitation that variable "R" or R1 can be either hydrogen or alkyl that is "substituted" with an electron-donating or withdrawing group. As it happens, nearly all organic substituents, and for that matter, inorganic substituents fall into one of these two categories. For example, when n = 3, and R_2 represents hydrogen, claim 1 is drawn to a method of using a peptide of the following formula to alleviate pain:

$$R_1\text{-CO-NH-CH}(R_3)\text{CO-NH-CH}(R_3)\text{CO-NH-CH}(R_3)\text{CO-NHR}$$

As applicants are no doubt aware, Leu-enkephalin is a well-known analgesic peptide, which has the sequence Tyr-Gly-Gly-Phe-Leu. This is encompassed by claim 1 when the substituent variables correspond as follows:

R_1 = phenylethyl that is substituted once with amino (*alpha-* to the carbonyl group) and once (on the phenyl ring) with hydroxyl;

R_{3a} = hydrogen;

R_{3b} = hydrogen;

R_{3c} = benzyl;

R = 1-(4-methylbutane) that is "substituted" with carboxy.

Given the compounds as recited, any and all peptides are encompassed, provided that they contain at least one *alpha*-amino acid. Even proteins having a molecular weight of 50 kD would be encompassed. Accordingly, the restriction given above is justified.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their divergent subject matter, restriction for examination purposes as indicated is proper.

*

In addition to the foregoing, applicants are required under 35 U.S.C. §121 to elect a single disclosed specie for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. A "specie" is a specific compound with **all** substituent variables **fully** accounted for. In the event that one of Groups 16-20 is chosen for examination, a second election is required, namely one of pain, a headache, or bipolar disease. In the event that any of Groups 21-25 is chosen for examination, a second election is required, i.e., a specific disorder such as Alzheimer's Disease, Huntington's Disease, Down's syndrome, or dementia.

Applicant is advised that a response to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a generic claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are witten in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP 809.02(a).

Should applicant traverse on the ground that the species are not patentable distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. §103 of the other invention. Applicant is advised that for the response to this requirement to be complete, an election of the invention to be examined must be indicated, even if the requirement is traversed (37 C.F.R. 1.143).

Applicant is reminded that upon cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a diligently filed petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(h).

✺

Applicants are requested, but not yet required, to explain whether claim 58 contains a typographical error in the structural formula. It appears that the following may be intended:

$$Ar\text{-}CH_2\text{-}NH\text{-}CO\text{-}CH(CH_2Q)\text{-}\mathbf{NH}\text{-}COCH_3$$

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David Lukton whose telephone number is 703-308-3213. The examiner can normally be reached Monday-Friday from 9:30 to 6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher Low, can be reached at (703) 308-2923. The fax number for the organization where this application or proceeding is assigned is 703-872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

DAVID LUKTON
PATENT EXAMINER
GROUP 1600